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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,833	11/20/2002	Anil B. Mukherjee	4239-61375	8664

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/019,833	MUKHERJEE ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,9-19,21-38 and 47* is/are pending in the application.

4a) Of the above claim(s) *9-17 and 24-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,18,19,21-23,47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3-5, 18, 19, 21-23 and 47 are under consideration.

2. Applicants' remarks regarding Restriction filed on 3/2/07 is acknowledged.

Applicants state that the pathology of SLE is not associated with the glomerulopathies as SLE is caused by IgA deficiency while IgA nephropathy is caused by deposits of IgA antibodies. Thus, the claimed invention contributes a special technical feature over the prior art.

However, the originally restricted claims filed on 9/27/06 are drawn to method of treating IgA mediated disorders (claim 1) and the claimed invention encompasses IgA mediated disorders caused by IgA deficiency as well.

As referred in the original restriction, Applicant's inventions do not contribute a special technical feature when viewed over the prior art, or meet key critical elements, they do not have a single general inventive concept and so lack unity of invention. The FINALITY of the restriction requirement made in the office action mailed 12/04/06 is still deemed proper.

3. In light of Applicants' amendments to the claims, the following rejections remain.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 3-5, 18, 19, 21-23 and 47 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an a method of treating IgA mediated nephropathy with an agent comprising a human uteroglobin as set forth in SEQ ID NO:1, does not reasonably provide enablement for a method of treating IgA nephropathy by providing uteroglobin fragment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and/or use of the invention commensurate in scope with these claims for the reasons set forth in the office action mailed 12/4/06.

Applicants' arguments and the exhibits (B and C) filed on 3/2/07 have been fully considered but they were not persuasive.

Applicants' traversed the rejection based on that the amendments to the claims obviate the rejection. Applicants further traversed that the fragments of uteroglobin are well known in the art and the working examples were provided.

Contrary to the Applicants' assertion that the fragments are well known in the art as shown in the Exhibits B and C, not all the uteroglobin fragments are able to perform the intended use of the claimed invention. In Table 4 of the '562 patent (exhibit B), some uteroglobin fragments (MKKVLD, MNKVLD, MQMKKVLDS and GICPRFAHVI) do not achieve the PLA2 inhibitory activity.

Moreover, the applicants' provision of the working example (Example 6) is drawn to the full length uteroglobin and there is no working example of the uteroglobin fragments enabling the claimed invention.

Therefore, there is insufficient direction as to how to make and to use a composition comprising any fragments of uteroglobin which can be used as to whether such a desired effect can be achieved or predicted, as encompassed by the claims.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed uteroglobin formulation in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. Claims 1, 3-5, 18, 19, 21-23 and 47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the office action mailed 12/4/06.

Applicant is in possession of uteroglobin composition comprising SEQ ID NO:1 but applicant is not in possession of an uteroglobin composition comprising any fragments of uteroglobin.

Applicants' traversed the rejection based on that the amendments to the claims obviate the rejection. Applicants further traversed that the fragments of uteroglobin with the biological function are disclosed in the specification.

However, the SEQ ID NO:1-4 as applicants stated as fragments are indeed full length of the uteroglobin from different species. Furthermore, as discussed above, MQMKKVLDS fragment as described in SEQ ID NO:20 did not have uteroglobin activity.

Moreover, Applicants define uteroglobin fragment as any 6 or more of uteroglobin amino acid residues and the uteroglobin consisting of 70 amino acids. There is insufficient written description encompassing a fragment. Therefore, Applicant does not possess of scope of claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. The following new grounds of rejections are necessitated by Applicant's amendments filed on 3/2/07.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 3-5, 18, 19, 21-23 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification and the claims as originally filed do not provide a clear support for the phrase "that retains the biological activity of uteroglobin". The specification on p. 9 discloses the derivatives of uteroglobin retains the biological activity of uteroglobin and no biological activity was associated with the uteroglobin fragments.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1. 3-5, 18, 19, 21-23 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/53846 (of record) in view of Cederholm et al (Proc. Natl. Acad. Sci. 1998, vol. 85, p.4865-4868, newly cited).

The '846 publication teaches that the method of treating IgA mediated autoimmune disorders including diabetic nephropathy, glomerulosclerosis, idiopathic nephropathy using human uteroglobin as in SEQ ID NO:1 of claimed (p. 18, claims 23-39 in particular).

The '846 publication further teaches that the human uteroglobin is about 95% pure (claims 9-10, in particular), the routes of administration includes ophthalmic, intravenous, systemic or oral (claims 21-23, in particular) and in combination with corticosteroid (claim 67, in particular).

Moreover, the '846 publication teaches that uteroglobin plays a central role in prevention of fibronectin deposition (p. 6, in particular).

The '846 publication does not teach the IgA mediated autoimmune disorder being IgA nephropathy.

However, Cederholm et al. teach that IgA nephropathy is caused by IgA deposits and patients with IgA nephropathy have circulating IgA antibodies bound to collagen (the binding site of fibronectin). The presence of IgA-fibronectin complex in serum and the binding of this complex to collagen demonstrate the necessity of removing fibronectin from serum (abstract, introduction, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to remove IgA-fibronectin complex as taught by Cederholm et al. with uteroglobin as taught by the '846 publication.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '846 publication teaches the removal or inhibition of fibronectin deposits are useful to treat various IgA mediated autoimmune disorders especially various renal disorders (p. 6, 18, claims 21-23, in particular). Cederholm et al. teach that IgA forms a complex with fibronectin and the removal of fibronectin by addition of uteroglobin also results IgA removal.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Claims 1. 3-5, 18, 19, 21-23 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,255,281 B1 (of record) as is evidenced by the specification disclosure on p. 2-3 in view of Cederholm et al (Proc. Natl. Acad. Sci. 1998, vol. 85, p.4865-4868, newly cited).

The '281 patent teaches that the method of treating IgA mediated autoimmune disorders glomerulosclerosis, Fn-deposit glomerulonephritis, glomerulopathies and nephropathy using human uteroglobin as in SEQ ID NO:1 of claimed (col. 1, lines 33-41, col. 9, lines 36-44, Exmple 11, in particular).

The '281 patent further teaches that the human uteroglobin is about 99% pure (c col. 10, lines 65-68, in particular), the routes of administration intravenous, systemic or oral (Example 11, in particular) and in combination with corticosteroid (Example 2, in particular).

Moreover, the '281 patent teaches that uteroglobin plays a central role in prevention of fibronectin deposition (col. 9, in particular).

As a patient is diagnosed with the above mentioned diseases, "identifying a subject..." before administering uteroglobin is inherently achieved.

As is evidenced by the p. 2 of the instant application, glomerulopathies encompass the IgA nephropathy.

The '281 patent does not teach the IgA mediated autoimmune disorder being IgA nephropathy.

However, Cederholm et al. teach that IgA nephropathy is caused by IgA deposits and patients with IgA nephropathy have circulating IgA antibodies bound to collagen (the binding site of fibronectin). The presence of IgA-fibronectin complex in serum and the binding of this complex to collagen demonstrate the necessity of removing fibronectin from serum (abstract, introduction, in particular).

Therefore, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to remove IgA-fibronectin complex as taught by Cederholm et al. with uteroglobin as taught by the '281 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the '281 patent teaches the removal or inhibition of fibronectin deposits are useful to treat various IgA mediated autoimmune disorders especially various renal disorders (col. 9, in particular). Cederholm et al. teach that IgA forms a complex with fibronectin and the removal of fibronectin by addition of uteroglobin also results IgA removal.

From the teachings of the references, one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. No claims are allowable.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
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May 3, 2007

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